UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,915	07/22/2003	D. Russell Pflueger	QMI-3077	7109

23410 7590 07/08/2010

Vista IP Law Group LLP
2040 MAIN STREET, Suite 710
IRVINE, CA 92614

EXAMINER	
PATEL, NIHIR B	
ART UNIT	PAPER NUMBER
3772	

MAIL DATE	DELIVERY MODE
07/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,915	PFLUEGER ET AL.	
	Examiner	Art Unit	
	NIHIR PATEL	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Pre-Brief filed on 12/13/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-55,66-68,70-78,80-83 and 85-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *82,83 and 85-92* is/are allowed.

6)☒ Claim(s) *52-55,66-68,70-76,80,81,93,94,98-102 and 104-107* is/are rejected.

7)☒ Claim(s) *77, 78, 95-97 and 103* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *DE 199 20 114 A1* .

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on December 23rd, 2009 with respect to claims 52-55, 66-68, 70-78, 80-83 and 85-107 have been fully considered and are persuasive. The previous rejection of the office action dated July 23rd, 2009 has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **93, 94, 100, 102 and 104-106** are rejected under 35 U.S.C. 102(b) as being anticipated by Fege (DE 19920114 A1).

4. **As to claim 93,** Fege teaches an apparatus for treating at least one of sleep apnea and snoring comprising an appliance comprising an elongated loop comprising first and second end portions **(see fig. 3 below)** and two spaced apart elongated elements **(see fig. 3 below)** extending between the first and second end portions, the appliance being sized for introduction into an oropharyngeal region **36 (see fig. 1)** of a human or animal and deployable in a C-shaped **(see figs. 1 and 3)** deployed configuration in which at least one of the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region **(see figs. 1-3; pages 1 and 2)**.

5. **As to claim 94,** Fege teaches an apparatus wherein the appliance defines an open interior space between the spaced apart elongated elements **(see fig. 3 below).**

6. **As to claim 100,** Fege teaches an apparatus for treating at least one of sleep apnea and snoring comprising an appliance comprising a single continuous loop comprising first and second rounded end portions **(see fig. 3; page 2)** and two spaced apart elongated elements extending between the first and second end portions **(see fig. 3; page 2)** such that the loop defines an open interior space between the spaced apart elongated elements **(see fig. 3)**, the appliance being sized for introduction into an oropharyngeal region **36** of a human or animal and deployable in a C-shaped deployed configuration **(see fig. 3)** in which the elongated elements extending generally laterally across the posterior wall and the first and second end portions bearing against and providing an opening force against the lateral walls of the oropharyngeal region **(see figs. 1 and 3).**

7. **As to claim 102,** Fege teaches a method for treating at least one of sleep apnea and snoring comprising the steps of providing an appliance comprising a continuous loop comprising first and second end portions **(see fig. 3; page 2)** and two spaced apart elongated elements extending between the first and second end portions **(see fig. 3; page 2)**; introducing the appliance into an oropharyngeal region **(see figs 1 and 3)**; and releasing the appliance within the oropharyngeal region such that the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region **(see figs. 1 and 3)**.

8. **As to claim 104,** Fege teaches a method of placing the appliance at least partially in or beneath the mucosal layer of the oropharyngeal region **(see fig. 3; pages 1 and 2)**.

9. **As to claim 105,** Fege teaches a method step of introducing the appliance in a deformed configuration, and wherein releasing the appliance within the oropharyngeal region allows the appliance to reconfigure to a deployed second configuration within the oropharyngeal region **(it is inherent that before the device is inserted into the patient that the device will be in the first configuration and will deform into a second configuration different from the first configuration when inserted into the user)**.

10. **As to claim 106,** Fege teaches a method step wherein the deployed second configuration comprises a C-shaped configuration **(see fig. 3 below).**

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims **52-55, 66-68, 70-76, 80, 81, 98, 99, 101 and 107** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fege (DE 19920114 A1) in view of Conrad et al. (US 6,250,307).

14. **As to claims 52, 99, 101 and 107,** Fege substantially discloses a method for treating sleep apnea in a human or an animal having an oropharyngeal region with lateral and posterior walls, a soft palate, a valecullar space and an epiglottis **(see page 1; 8th paragraph)**, the method comprises providing an appliance **52 (see fig. 3; page 2)** located below a soft palate **8** of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal region **36 (see figs. 1-3)** of the human or animal, the appliance so provided having at least two laterally positioned elements **(see fig. 3)** substantially longitudinally spaced apart from each other to define an open interior space therebetween **(see fig. 3)** and providing an opening force against the lateral walls of the oropharyngeal region but does not disclose the device being made of biocompatible material. Conrad discloses a device that is made of biocompatible **(see co9l. 5 lines 50-67).** Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Fege's invention by manufacturing the device using a biocompatible material as taught by Conrad so that the user's body adjust quickly to the device and to prevent the user from being infected by the device.

15. **As to claim 53,** Fege substantially discloses a method step wherein the appliance, when located in the oropharyngeal region **36**, is effective in maintaining patency of the oropharyngeal region during natural sleep of the human or animal without causing substantial interference with at least one natural function of the epiglottis **(see page 1)**.

16. **As to claim 54,** Fege substantially discloses a method step of providing includes inserting the appliance into the oropharyngeal region **36** while the appliance is in a first configuration and allowing the appliance to reconfigure to a second configuration within or in proximity to the oropharyngeal region **(see page 2)**.

17. **As to claim 55,** Fege substantially discloses a method step of inserting the appliance into the oropharyngeal region through a mouth of the person or animal **(see figs. 1-3)**.

18. **As to claim 66,** Fege substantially discloses a method step of placing the appliance at least partially in or beneath the mucosal layer of the lateral and posterior walls of the oropharyngeal region **(see fig. 1-3 and page 2)**.

19. **As to claim 67,** Fege substantially discloses a method step of placing the appliance completely across the the posterior wall of the oropharyngeal region **(see fig. 1; page 2)**.

20. **As to claim 68,** Fege substantially discloses a method step of providing the appliance in a deformed first configuration, inserting the appliance into the oropharyngeal region and allowing the appliance to reconfigure to a deployed second configuration within the oropharyngeal region **(it is obvious to one having ordinary skill in the art that before the device is inserted into the patient that the device will be in the first configuration and will deform into a second configuration different from the first configuration when inserted into the user)**.

21. **As to claim 70,** Fege substantially discloses a method step wherein the device has at least one of the elements extending across the posterior wall of the oropharyngeal region **(see fig. 1; page 2)**.

22. **As to claim 71,** Fege substantially discloses a method step wherein the at least two elements are coupled together **(see fig. 3)**.

23. **As to claim 72,** Fege substantially discloses a method step wherein the at least two elements are portions of the same structure **(see fig. 3)**.

15. **As to claim 73,** Fege substantially discloses a method step wherein the appliance has a lateral dimension and a longitudinal dimension perpendicular to the lateral dimension which is less than the lateral dimension when the appliance is so provided **(see fig. 3 below)**.

16. **As to claim 74,** Fege substantially discloses a method step wherein the appliance is sized and structured so that each of the at least two elements extend across the posterior wall and at least a portion of one of the lateral walls when the appliance is so provided **(see figs. 1 and 3)**.

17. **As to claim 75,** Fege substantially discloses a method step wherein the appliance is sized and structured so that each of the at least two elements extend across the posterior wall and at least a portion of both the lateral walls when the appliance is so provided **(see figs. 1 and 3)**.

18. **As to claim 76,** Fege substantially discloses a method step wherein the appliance has an open concave loop configuration when so provided **(see fig. 1)**.

19. **As to claim 80,** Fege substantially discloses the claimed invention; see rejection of claim 52 above, but does not disclose the appliance that is made of an elastic spring memory material. Conrad discloses a device that is made an elastic spring memory material **(see col. 5 lines 50-67).** Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Fege's invention by manufacturing the device using an elastic spring memory material as taught by Conrad so that the device can move from a first configuration to a second configuration so as to provide the user comfort and to ensure that there is no disturbance during sleep.

20. **As to claim 81,** Fege substantially discloses the claimed invention; see rejection of claim 52 above, but does not disclose the appliance that is made of nitinol. Conrad discloses a device that is made nitinol **(see col. 6 lines 1-3).** Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Fege's invention by manufacturing the device using nitinol as taught by Conrad so that the user's body adjust quickly to the device and to prevent the user from being infected by the device.

21. **As to claim 98,** Fege substantially discloses the claimed invention; see rejection of claim 93 above, but does not disclose the appliance expanding to a diameter greater than 32 mm in the deployed configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Fege's invention by providing an appliance that expands to a diameter greater than 32 mm in the deployed configuration so that the device opens the airway so that the user can breathe easily while sleeping, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. ***In re Aller,*** **105 USPQ 233.**

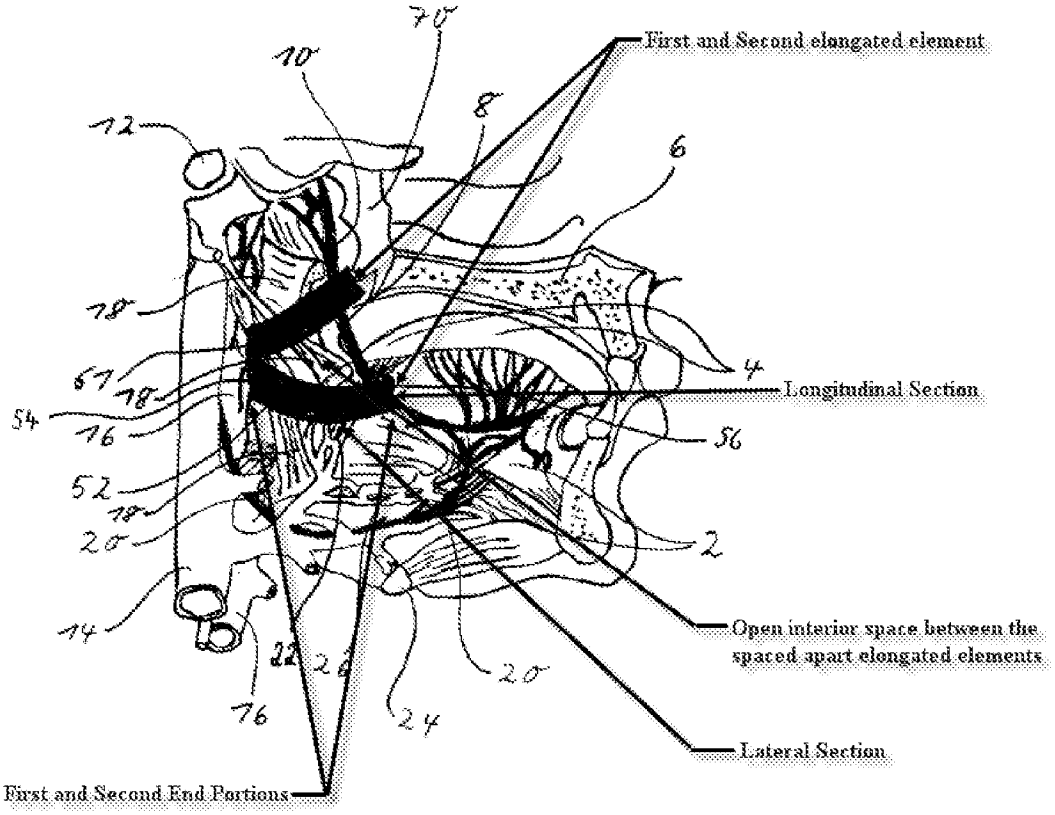

Fig. 3

Allowable Subject Matter

22. Claims **82, 83 and 85-92** are allowed. The prior art does not teach the first end and the second end defining a gap therebetween extending outwardly away from the first and second curved elements having a gap length which is reduced relative to the curved length of each of the curved elements.

23. Claims **77, 78, 95-97 and 103** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose a method step wherein

the appliance, when so provided is effective to support or reinforce the oropharyngeal region without reacting with tissue in the oropharayngeal region. The prior art also does not disclose plurality of struts extending across the open interior space.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772
/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772